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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/533,538

05/02/2005

Kei Kiribayashi

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1631

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07/06/2009

OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C.  
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ALEXANDRIA, VA 22314

EXAMINER

HENRY, MICHAEL C

ART UNIT

PAPER NUMBER

1623

NOTIFICATION DATE

DELIVERY MODE

07/06/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/533,538	<b>Applicant(s)</b> KIRIBAYASHI ET AL.	
	<b>Examiner</b> MICHAEL C. HENRY	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03/17/09.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The finality of the rejection of the last Office action 03/17/09 is withdrawn.

The following office action is a responsive to the Amendment filed, 03/17/09.

The amendment filed 03/17/09 affects the application, 10/533,538 as follows:

1. Claims 11 and 21 have been amended. Claims 1-5 have been canceled. Upon further consideration it was determined that the indicated allowable subject matter of the prior office action mailed 11/18/08 was not appropriate. Consequently, this allowable subject matter is withdrawn. The rejections made under 35 U.S.C. 103(a) are maintained.
2. The responsive to applicants' amendments and arguments is contained herein below

Claims 11-32 are pending in the application

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isono et al. (US 5,871,477).

Claim 11 is drawn to a peritoneal dialysis method for treating a peritoneal injury or for treating a cell injury caused by sugar comprising: administering to a patient having a peritoneal injury or a cell injury caused by sugar a dialysate comprising adenosine triphosphate or a salt thereof. Claim 12 is drawn to the peritoneal dialysis method of claim 11, wherein said patient is

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suffering from a renal disease, and said dialysate is administered intraperitoneally via a catheter implanted in the peritoneal cavity. Claims 13-17 are drawn to said method wherein the adenosine triphosphate or a salt thereof is of specific concentration range, wherein the composition further comprises glucose, and an electrolyte, glucose of specific concentration range and further administering high level glucose.

Isono et al. disclose a peritoneal dialysate composition comprising 1 to 8 g/dL glucose (i.e., 1,000- 8000 mg/dL) and electrolytes; wherein said composition can be used a peritoneal dialysate (see col. 2, lines 5 to 46). Furthermore, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46). Also, Isono et al. disclose that the peritoneal dialysate can be used to treat acute or chronic peritonitis (see col. 13, lines 47-51 and col. 19, lines 50-53). In addition, Isono et al. disclose that organic acids such as lactic acid and citric acid can be used (see col. 2, lines 5 to 46, especially lines 34-46). This suggests that said peritoneal composition or dialysate by Isono et al. can be administered into the peritoneal cavity to treat peritoneal injuries or peritoneal cell injuries such as peritonitis. It should be noted that the examiner considers peritonitis as a peritoneal injury or peritoneal cell injury. In fact, it should be noted that applicants acknowledge in their specification that examples of the peritoneal injuries include peritonitis, sclerotic encysted peritonitis, intractable prolonged peritonitis, and general peritonitis (see page 2, paragraph [0026] of applicants' specification).

The difference between applicant's method and the method suggested by Isono et al. is that Isono et al.'s composition does not contain adenosine triphosphate. However, Isono et al.

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disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Isono et al., to treat peritoneal injury or a cell injury in a subject by administering a composition comprising a combination of adenosine triphosphate, glucose, and electrolytes as a peritoneal dialysate into the peritoneal cavity of said subject.

One having ordinary skill in the art would have been motivated in view of Isono et al., to treat peritoneal injury or a cell injury in a subject by administering a composition comprising a combination of adenosine triphosphate, glucose, and electrolytes as a peritoneal dialysate into the peritoneal cavity of said subject. It should be noted that it is obvious to a skilled artisan to prepare said peritoneal dialysate or composition with osmotic pressure or osmolarity that would be physiological compatible when administered to said subject. It should be noted that the use of peritoneal dialysis to treat patients with renal disease is extremely common in the art and is well within the purview of a skilled artisan.

Claim 18 is drawn to a treating method for peritoneal injury, characterized by administering an effective amount of adenosine triphosphate or a salt thereof to a subject in need thereof. Claim 19 is drawn to a treating method for cell injury caused by sugar, characterized by administering an effective amount of adenosine triphosphate or a salt thereof to a subject in need thereof. Claim 20 is drawn to the method as described in claim 19, wherein the cell injury caused by sugar is peritoneal mesothelial cell injury caused by glucose. Claims 31-32 are drawn to said method comprising administering a solution containing ATP or salt thereof, glucose of specific concentration range, and electrolytes.

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Isono et al. disclose a peritoneal dialysate composition comprising 1 to 8 g/dL glucose (i.e., 1,000- 8000 mg/dL) and electrolytes; wherein said composition can be used a peritoneal dialysate (see col. 2, lines 5 to 46). Furthermore, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46). Also, Isono et al. disclose that the peritoneal dialysate can be used to treat acute or chronic peritonitis (see col. 13, lines 47-51 and col. 19, lines 50-53). In addition, Isono et al. disclose that organic acids such as lactic acid and citric acid can be used (see col. 2, lines 5 to 46, especially lines 34-46). This suggests that said peritoneal composition or dialysate by Isono et al. can be administered into the peritoneal cavity to treat peritoneal injuries or peritoneal cell injuries such as peritonitis. It should be noted that the examiner considers peritonitis as a peritoneal injury or peritoneal cell injury. In fact, it should be noted that applicants acknowledge in their specification that examples of the peritoneal injuries include peritonitis, sclerotic encysted peritonitis, intractable prolonged peritonitis, and general peritonitis (see page 2, paragraph [0026] of applicants' specification).

The difference between applicant's method and the method suggested by Isono et al. is that Isono et al.'s composition does not contain adenosine triphosphate. However, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate ((see col. 2, lines 5 to 46, especially lines 34-46).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Isono et al., to treat peritoneal injury or a cell injury in a subject by administering a composition comprising a combination of adenosine triphosphate, glucose, and electrolytes as a peritoneal dialysate into the peritoneal cavity of said subject.

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One having ordinary skill in the art would have been motivated in view of Isono et al., to treat peritoneal injury or a cell injury in a subject by administering a composition comprising a combination of adenosine triphosphate, glucose, and electrolytes as a peritoneal dialysate into the peritoneal cavity of said subject. It should be noted that it is obvious to a skilled artisan to prepare said peritoneal dialysate or composition with osmotic pressure or osmolarity that would be physiological compatible when administered to said subject. It should be noted that the use of peritoneal dialysis to treat patients with renal disease is extremely common in the art and is well within the purview of a skilled artisan. It should be noted that it is obvious to a skilled artisan to prepare said peritoneal dialysate or composition with osmotic pressure or osmolarity that would be physiological compatible when administered to said subject.

In claim 21, applicant claims a peritoneal dialysis method for treating a peritoneal injury or for treating a cell injury caused by sugar, comprising: administering into the peritoneal cavity of a subject having a peritoneal injury or a cell injury caused by sugar an effective amount of a composition comprising adenosine triphosphate or a salt thereof. Claims 22-30 are drawn to said method wherein said composition used contains specific electrolytes, organic acid, lactic acid and which has specific osmotic pressure, and wherein the subject has specific conditions.

Isono et al. disclose a peritoneal dialysate composition comprising 1 to 8 g/dL glucose (i.e., 1,000- 8000 mg/dL) and electrolytes; wherein said composition can be used as a peritoneal dialysate (see col. 2, lines 5 to 46). Furthermore, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46). Also, Isono et al. disclose that the peritoneal dialysate can be used to treat acute or chronic peritonitis (see col. 13, lines 47-51 and

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col. 19, lines 50-53). In addition, Isono et al. disclose that organic acids such as lactic acid and citric acid can be used (see col. 2, lines 5 to 46, especially lines 34-46). This suggests that said peritoneal composition or dialysate by Isono et al. can be administered into the peritoneal cavity to treat peritoneal injuries or peritoneal cell injuries such as peritonitis. It should be noted that the examiner considers peritonitis as a peritoneal injury or peritoneal cell injury. In fact, it should be noted that applicants acknowledge in their specification that examples of the peritoneal injuries include peritonitis, sclerotic encysted peritonitis, intractable prolonged peritonitis, and general peritonitis (see page 2, paragraph [0026] of applicants' specification).

The difference between applicant's method and the method suggested by Isono et al. is that Isono et al.'s composition does not contain adenosine triphosphate. However, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate ((see col. 2, lines 5 to 46, especially lines 34-46)

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Isono et al., to treat peritoneal injury or a cell injury in a subject by administering a composition comprising a combination of adenosine triphosphate, glucose, and electrolytes as a peritoneal dialysate into the peritoneal cavity of said subject.

One having ordinary skill in the art would have been motivated in view of Isono et al., to treat peritoneal injury or a cell injury in a subject by administering a composition comprising a combination of adenosine triphosphate, glucose, and electrolytes as a peritoneal dialysate into the peritoneal cavity of said subject. It should be noted that it is obvious to a skilled artisan to prepare said peritoneal dialysate or composition with osmotic pressure or osmolarity that would be physiological compatible when administered to said subject. It should be noted that the use of



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peritoneal dialysis to treat patients with renal disease is the extremely common in the art and is well within the purview of a skilled artisan. It should be noted that it is obvious to a skill artisan to prepare said peritoneal dialysate or composition with osmotic pressure or osmolarity that would physiological compatible when administered to said subject.

### ***Response to Arguments***

Applicant's arguments with respect to claims 11-32 have been considered but are moot in view of the rejections set forth above.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry  
June 29, 2009.

/Shaojia Anna Jiang/  
Supervisory Patent Examiner  
Art Unit 1623